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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,874	12/22/1999	MARC MEHRZAD JALISI	25141-0430	6721

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EXAMINER
ASSADI, KATHRYN L

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 12/06/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/470,874	Applicant(s) JALISI ET AL.	
	Examiner Kathryn L Assadi	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/22/99* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 and 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fagan et al. (US 5,720,300).

Fagan et al., discloses an elongate member (52,56) formed at least in part of a composite elongate core (50) formed at least in part of a precipitation hardened material such as an alloy composed of nickel, cobalt, molybdenum, and chromium (MP35N and Eligiloy) having a small amount of iron (Column 5, lines 2-4), 455PH stainless steel or stainless steel alloy 1RK91 (Abstract, lines 8-10). 455PH is known to be a chromium-nickel based single stage martensitic precipitation hardenable stainless steel (Column 6, lines 1-4; Column 10, lines 46-49). Fagan also teaches that the alloys are precipitation hardenable by controlled heat treatment (Column 10, lines 54-55).

Fagan et al., further discloses in Column 10, lines 65-66, that the alloy can have a modulus of elasticity compared to that of type 304 stainless steel (approximately 28,000,000 to 29,000,000 p.s.i.). In addition, the alloy can have a tensile strength as low as about 150 k.s.i. but preferably about 250 k.s.i. (Column 10, lines 63-66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fagan et al. (US 5,720,300) in view of Reiss et al. (WO 98/22024).

Reiss et al. discloses a guidewire (10) comprising an elongated core element (12) manufactured from a martensitic alloy that is heat-treated to render a fully hardened core throughout its cross sectional area (see Abstract). Reiss further discloses examples of temperature hardened, martensitic steel alloys such as carbon, manganese, chromium, silicone, molybdenum, iron, and nickel. As can be seen from page 7, Table II, line 9, the amount of nickel that can be used is negligible. Therefore, it would have been obvious to one having ordinary skill in the art to produce a precipitation hardenable stainless steel that is essentially nickel-free or contains less than about 1% nickel.

Claims 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fagan (US 5,720,300) in view of Fariabi (US 5,636,641).

Fariabi discloses a high strength alloy containing cobalt, nickel, and chromium and particularly to a composite product having a portion formed of the high strength colbalt-nikel-chromium alloy and a portion formed of pseudoelastic alloy such as NiTi

alloy (Column 2, lines 16-19). Fariabi further discloses that one embodiment of the invention is an elongated member formed at least in part, of alloy comprising about 28%-65% cobalt, about 2%-40% nickel, about 5%-35% chromium an up to about 12% molybdenum. Other alloying components include up to 20% tungsten, 20% iron and 3% manganese. The alloy may also contain inconsequential amounts of other alloying constituents, as well as impurities, typically less than 0.5% each (Column 2, lines 21-30). Fariabi further states that in another embodiment of the invention, the cobalt-nickel-chromium alloy is formed into a composite structure with a NiTi alloy (Column 2, lines 51-53). Therefore, it would be obvious to one with ordinary skill in the art that the inner core element and the first layer portion could be formed from different material. It is obvious that either the inner core or the first layer portion could be formed from superelastic NITINOL and precipitation hardenable material. It is also obvious that the second layer portion of the elongate core could be formed from a material similar to that of the inner core element material.

In Figure 1, Fariabi shows the distal section (17) of the core member (11), which is disposed primarily within the coil (14), and is tapered to sequentially smaller diameters to provide gradually increasing flexibility along the length of the distal portion of the guidewire (10). Figure 2 depicts a guidewire (30) with a construction wherein the tapered distal section (31) of the core member (32) extends to the plug (33) which connects the distal end of the core member to the distal end of the helical coil (34) disposed about the distal section of the core member. The proximal section (35) of the core member (32) is of composite construction with a sheath (36) of high strength Co-

Ni-Cr alloy and an inner member (37) of a pseudoelastic NiTi alloy. The high strength sheath (36) is removed from the core member to form the tapered distal section (31) to increase the flexibility of the distal section of the guidewire (30). It would be obvious to one with ordinary skill in the art that the inner core element is at least partially exposed at the distal flexible section of the distal segment of the composite elongate member and that the first layer portion is at least substantially exposed at the proximal portion of the distally tapered section of the distal segment of the composite elongate core.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Assadi whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLA
November 26, 2001

ANGELA D SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700